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(54) **TRANSINTIMAL RECANALISATION DEVICE**

TRANSINTIMALE REKANALISATIONSEINRICHTUNG

DISPOSITIF DE RECANALISATION TRANSINTIMA

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(56) References cited:
EP-A- 0 269 763
GB-A- 2 124 503
US-A- 4 511 356

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Description

This invention relates to an arterial transintimal recanalisation device.

In middle age, over 40% of males have evidence of significant vascular impairment due to arterial fat deposits. This generalised disease, atherosclerosis, may be heralded by relatively minor, but nonetheless disabling, symptoms of lower limb peripheral vascular disease. This may range in presentation from mild intermittent claudication (limp) which may or may not limit lifestyle, to critical ischaemia with rest pain and/or ulceration or gangrene with an associated risk to life and limb. Management involves attention to the presenting clinical problem, which may be acute and necessitate immediate intervention. Surgery has been the mainstay of intervention for some three decades, however minimally invasive management by balloon angioplasty and related techniques has become of rapidly increasing importance.

In these newer procedures a guidewire is inserted percutaneously through an arterial stenosis or occlusion using x-ray control. A balloon is then passed over the guidewire and inflated in the obstructed segment. These procedures are cost effective, very low risk (about 0.4%) and are performed under a local anaesthetic; discomfort is minimal.

Technical failure occurs in about 20% of occlusions treated and is due to failed guidewire passage (due to heavy calcification, vessel perforation or, most commonly, subintimal passage of the guidewire), elastic recoil of the arterial wall, or acute occlusion due to spasm or thromboembolism. Elastic recoil and acute occlusion can be managed by alternative techniques. Where there has been subintimal guidewire passage, success may necessitate breaking through the intima into the patent, distal lumen. Whilst this can be attained in about 50% of cases in the remainder the intima resists attempts to pass a guidewire through its substance due to a combination of the strength and integrity of the intima and the necessarily atraumatic construction of the guidewires used in these procedures.

An aim of the present invention is to provide a transintimal recanalisation device which overcomes the problem of the intima resisting passage of a guidewire through its substance.

A further aim of the present invention is to provide a method of assembling a transintimal recanalisation device.

In accordance with a first aspect of the present invention there is provided a flexible transintimal recanalisation device adapted to be guided through the vasculature of a patient comprising a guide tube, a flexible needle having a bevelled end and located in said tube, wherein said needle is movable from a covered position wherein said bevelled end is within the tube to an uncovered position in which said bevelled end is exposed, and means enabling said bevelled end to adopt a desired orientation with respect to the tube.

Preferably, said tube has a bend in its length and the needle has a bend in its length which conforms with the bend of the tube, thereby orientating the bevelled end with respect to the tube.

It is preferred that said needle is hollow. Preferably, said device further comprises means for manoeuvering the needle with respect to the tube.

The means for enabling said bevelled end to adopt a desired orientation with respect to the tube may be provided by said manoeuvering means.

In a preferred embodiment of the invention said manoeuvering means comprises a first body connected to an end of the needle spaced from the bevelled end. Preferably said first body is provided with a first aperture therethrough in communication with said hollow needle.

It is preferred that said device further comprises a second body connected to an end of said tube and wherein said second body is provided with a first aperture therethrough to allow the passage of said needle.

Said first body may be provided with a second aperture extending from said first aperture to a surface of the body. Similarly, said second body may be provided with a second aperture extending from said first aperture to a surface of the body.

Said first and second bodies may be provided with cooperating alignment means whereby cooperation of said means results in the bevelled end of the needle adopting a desired orientation.

Preferably, said alignment means comprises a cooperating protrusion and recess.

In a preferred embodiment of the invention, said first and second bodies have means for indicating the relative position of the bevelled end of the needle with respect to an end of the tube spaced from said second body.

Said indicating means may be provided by the cooperation of a protrusion with one of at least two spaced apart apertures.

The first and second bodies preferably form a luer arrangement.

It is preferred that said needle and/or said tube is or are formed from a material having shape memory properties such that the needle or tube will adopt said bend at a given temperature. The material may be a nickel titanium alloy.

In accordance with a second aspect of the present invention there is provided a method of assembling a flexible transintimal recanalisation device adapted to be guided through the vasculature of a patient having a guide tube, a flexible needle having a bevelled end and located in said tube, a body connected to an end of the needle spaced from said bevelled end and means enabling the bevelled end to adopt a desired orientation with respect to the tube wherein said method comprises the steps of threading the end of the needle spaced from said bevelled end through the guide tube until it extends beyond an end of the tube and connecting said

body to the end of the needle.

The advantage of this 'back-loading' method is that it enables the device to be assembled without the need to pass the bevelled end of the needle through the length of the tube and hence reduces the risk of the bevelled end being damaged during assembly.

According to a third aspect of the invention there is provided a method of assembling a flexible transintimal recanalisation device adapted to be guided through the vasculature of a patient having a guide tube with a bend in its length, a flexible hollow needle having a bevelled end and located in said tube and means enabling the bevelled end to adopt a desired orientation with respect to the tube wherein said method comprises the steps of threading a stylette into the tube until an end of the stylette extends beyond the bevelled end of the needle, inserting the needle and stylette into the tube until a desired position is reached and withdrawing the stylette.

Once the device has been assembled it may no longer be possible to disconnect the body from the needle and hence if the needle is removed, for example, in order to be cleaned, it will not be possible to reassemble the device by the above-mentioned 'back-loading' method. In consequence, the above method is particularly advantageous since it enables the device to be reassembled with a degree of protection for the bevelled end of the needle which passes through the length of the tube.

An embodiment of the present invention will now be described, by way of example only, with reference to the accompanying drawings, wherein:-

Figure 1 is a sectioned elevation through the principle components of a device according to the invention; and

Figure 2 is an exploded pictorial illustration of the principle components of the device shown in figure 1.

The outer catheter 3 (figures 1 and 2). This is of polyamide or other radiopaque, plastic construction, is tapered to a catheter endhole of in the region of 0.95mm for passage over a conventional, wound 0.9mm or similar guidewire. Length of 3 is dependent on the vessel involved, generally 65cms. Diameter should be in the region of 1.67mm (5 French).

At the proximal end is a hub 12 with luer sized syringe fitting S' in Figure 2 and a locking, free rotating collar 13 in Figures 1 and 2. The hub construction is such that it is possible to insert the curved end section of 2 through S' and into 3. 3 is normally straight (as shown by 3', Figure. 1) but will adopt a curved end section when the curved end section LD on 2 is fully assembled to 3 (illustrated in Figure 1).

The guide tube 2 (Figures 1 and 2). This is of flexible, radiopaque metal such as nickel titanium. Diameter is dependent on 1 and 3 but generally is in the region of 1mm (3 French). The length of 2 is such that tip D of 2 lies approximately 0.5mm behind tip E of 3 when 2 is assembled to 3. The shaft of 2 is straight apart from the end section LD in Figure 1 which has a curved angulation C which is equivalent in radius of curvature R to curved angulation C' on 1, as in Figure 1. The length LD on 2 is in the region of 4.5mm less than the length L'A on curved end section of 1 (i.e. length LD on 2 is of the order of 1.5 to 2cms). The curved end section LD on 2 commences at L on 2 such that when 1 is fully assembled and advanced into 2, point L on 2 coincides with point L' on 1 where L' is the point of commencement of the curved end section L'A on 1.

The proximal end of 2 is fitted with a hub 8 in Figures 1 and 2 with screw fittings 9 and 10 which accommodate locking collars 5 on 1 and 13 on 3, in Figures 1 and 2. There is a luer sized syringe fitting S within hub 8 as in Figure 2. A friction coupling 11 prevents rotation between 12 and 8 when these parts are mated.

The inner needle 1 (Figures 1 and 2). This is a flexible needle constructed of a radiopaque metal such as nickel titanium. The length of 1 is such that tip A of 1 projects approximately 4mms, X in Figure 1, beyond the tip E of catheter 3 when the transintimal recanalisation device is assembled with the bushes 4 on 1, 8 on 2 and 12 on 1 in Figure 2 fully mated.

The shaft of 1 is straight apart from end section L'A on 1 which is normally curved as shown by 1' in Figure 1. The radius of curvature R of end section L'A of 1 is equivalent to that of curved end section LD of 2 in Figure 1. The length L'A on 1 is in the region of 4.5mm greater than length LD on 2 (i.e. length L'A is of the order of 1.95 to 2.45cms). The curved end section L'A on 1 commences at L' on 1 such that when 1 is fully assembled and advanced into 2, point L' on 1 coincides with point L on 2 where L is the point of commencement of the curved end section LD on 2. In this situation (fully assembled), the curved end sections L'A on 1 and LD on 2 coincide, constraining the curved end section L'A on 1 to adopt its lowest energy level and ensuring a constant orientation of bevel B as in Figure 1. In this fully assembled arrangement, tip A of 1 lies approximately 4.5mm beyond tip D of 2.

Diameter is such that 1 will pass through 2 with about 0.05mm clearance and is of the order of 0.64mm (23 SWG). A low friction coating of inner needle 1 may be utilised. The inner lumen of 1 will allow passage of a 0.38mm, or similar, guidewire.

The proximal fitting of 1 is a hub 4 in Figures 1 and 2 with a luer sized syringe fitting 16 in Figure 2 and with a single orientation device 7 which, when fully engaged with 15 in Figures 1 and 2 and fixed using the collar 5, ensures that the curved end sections of 2 and 1 coincide both longitudinally (i.e. in start points L and L' of curved end sections L and L'A) and in radial orientation. In this situation there is a known orientation of bevel B to the hubs 4 and 8 in Figure 1. Marks or shape features (not illustrated) on the outer periphery of 6 and 8 may help to achieve this. Rotation between the fully assem-

bled hubs 4 and 8 in Figures 1 and 2 may be minimised by use of a friction coupling (not illustrated).

The engagement of single orientation device 7 with 15 in Figures 1 and 2 takes place over a distance slightly greater than the length X in Figure 1 (approx 6mms) and during this engagement there are two palpable clicks generated by pips on one plastic member corresponding with detents on the other (not illustrated). The first of these palpable clicks occurs when the tip A of 1 lies in its retracted position, about 1mm behind the distal end D of 2. The second occurs when 1 is fully extended such that tip A of 1 lies approximately 4.5mms beyond tip D of 2.

Alternatively, provision of an increased number of pips and detents will generate multiple clicks (or clickstops) throughout the extension process, indicating various positions of the needle tip up to full extension.

The hub assemblies 4, 8 and 12 on items 1, 2 and 3 in Figures 1 and 2 could be provided with side injection ports (not illustrated) to allow intraprocedural flushing with, eg., heparinised saline.

The advancement of the needle 1 will produce a resultant force on the tip A of 1 due to the constant orientation of B as in Figure 1. This vector tightens radius of curvature R on the extruded length DA of end section L'A on 1 in Figure 1 and assists tracking of the needle tip A towards and into the adjacent vessel lumen. In the fully extended position of 1, the angular direction of the tip A of 1 is constantly orientated by the engagement of hub items 7 and 15 in Figures 1 and 2 and is indicated by the visual marks and/or tactile features on the outer periphery of 6 and 8.

Guide tube 2 and inner needle 1 are normally supplied preassembled as the puncture device. During manufacture the puncture device may be assembled by back-loading the needle component 1 into guide tube 2 prior to the fitting of hub 4 to needle component 1 in Figures 1 and 2. Back-loading will minimise frictional effects of inner wall of guide tube 2 on tip A of 1 during assembly.

An alternative approach to the reduction of frictional effects during assembly could utilise the known shape memory properties of nickel titanium to achieve temperature dependent straightening of curved end sections LD on 2 and L'A on 1 prior to mating these components.

The puncture device is supplied with hub items 7 on 1 and 15 on 2 in Figures 1 and 2 pre-engaged at the first clickstop position and with collar 5 of 1 in Figures 1 and 2 fully slackened. In this situation, the tip A of inner needle 1 will be in its retracted position within guide tube 2. A detachable safety spacer (not illustrated) could be incorporated between hub items 7 on 1 and 15 on 2 in Figures 1 and 2 to prevent premature exposure of tip A of 1 from the puncture device.

Stylette (not illustrated). This optional accessory is a metal, rounded tip stylette of diameter approximately 0.38mm and with a proximal hub fitting. Length is such that when fully assembled to 1, stylette protrudes beyond tip A of 1 by about 0.6cm and produces a straightening effect on curved end section L'A of 1.

Whilst 1 and 2 will normally be supplied reassembled, if during use they are separated (for example for cleaning and flushing) and require reassembly, this may be assisted by assembly of stylette to 1, the resulting partial straightening effect on curved end section L'A on 1 assisting re-introduction of the tip A through hub 8 and into the lumen 2, the stylette also reducing impaction of the needle tip A of 1 against the inner wall of 2. Hub item 7 of 1 is then engaged into hub item 15 of 2, at the first clickstop position and the stylette removed, when tip A of 1 will be in its retracted position within guide tube 2.

Where shape memory properties are utilised in construction of guide tube 2 and inner needle 1, temperature dependant straightening of the curved end sections LD on 2 and L'A on 1 would facilitate reassembly of these items.

An ultrasonic doppler stylette (not illustrated). This may be provided to assist needle placement into the vessel lumen by detecting the doppler shift of flowing blood when the needle tip is directed towards a patent vessel lumen.

Use of shape memory properties of nickel titanium. The use of nickel titanium in construction of guide tube 2 and inner needle 1 would permit exploitation of the known shape memory properties of this material. The achievement of temperature dependent straightening of the curved end sections LD on 2 and L'A on 1 in the assembled puncture device would facilitate assembly of the puncture device to catheter 3 in Figure 1. On attaining normal body temperature (37°C) the end sections LD on 2 and L'A on 1 would regain their original curved configuration as shown by radius of curvature R in Figure 1.

Inner guidewire (not illustrated). This is of the order of 0.38mm diameter. Length is in the region of 160cms. Low friction coating will assist wire passage.

Inner recanalisation catheter (not illustrated). This final component is a plastic catheter of external diameter about 1mm (3 French) to allow passage through the lumen of 3 and tapered to an end hole of in the region of 0.43mm, to fit the inner guidewire used through the lumen of 1. The inner recanalisation catheter will be in the region of 5cms longer than 3. The hub of this catheter could be constructed to mate the hub and rotating collar 13, 12 of 3 in Figures 1 and 2 to passage as one unit.

The mode of use will now be described with the aid of drawings, Figures 1 and 2.

A conventional angioplasty will have been attempted but guidewire passage will have failed owing to a persistently subintimal position of the wire. The initial arterial puncture should be made obliquely, a perpendicular puncture may preclude introduction of item 2. The guidewire tip is positioned, under x-ray control, adjacent to the patent distal vessel lumen and in a subintimal position. The catheter used up to this point is

removed and replaced over the guidewire by a short, standard, angiographic sheath of internal diameter at least 0.167mm (0.5Fr) in excess of the outside diameter of 3, leaving the guidewire in position.

The transintimal recanalisation device is supplied sterile, in sealed packaging and is a single use device. The inner needle 1 and guide tube 2 are normally supplied preassembled as the puncture device. A stylette may be supplied to facilitate reintroduction of 1 into 2 should these items be separated during use. Alternatively, the use of shape memory properties could be used to facilitate reassembly of the puncture device.

The outer catheter 3 is flushed and loaded onto the guidewire and advanced through the sheath to the guidewire tip. The guidewire is removed.

The preassembled puncture device is examined to ensure that the tip A of inner needle 1 is in its retracted position with hub items 7 and 15 on Figures 1 and 2 engaged to the first clickstop and tip A of inner needle 1 lying unexposed, within tip D of guide tube 2. Collar 5 in Figure 2 should be fully slackened. The central lumen of 1 is flushed with heparinised saline introduced through luer fitting 16 of hub 4 of 1 and the puncture device is passed with care through the lumen of catheter 3, assisted if necessary by gentle rotation. Exploitation of the shape memory properties of nickel titanium would allow use of temperature dependent straightening of the curved end sections LD on 2 and L'A on 1 to further facilitate passage of the puncture device through the lumen of catheter 3.

It is essential that during the introduction of the puncture device into catheter 3 the operator ensures that inner needle 1 remains in the retracted position as shown by hub items 7 and 15 in Figures 1 and 2 remaining in their first clickstop position. Hubs 12 and 8 in Figures 1 and 2 are now locked together using collar 13.

A digital subtraction road map is made using contrast injection into the sheath and with the x-ray tube positioned to show the tip of the assembled device adjacent to and, in the plane imaged, maximally separated from the distal lumen. The curved end section of the assembled device can now be finely directed by gentle rotation of the hub assembly, assisted by the external marks or shapes on the hub assembly. Further contrast injections through the sheath may be necessary during this process, until fluoroscopy in two planes shows the tip of the assembled device to appear directed exactly at the patent, distal vessel lumen and separated from it only be the intimal layer. This process may be further refined by use of an optional ultrasonic stylette which uses a doppler signal to assist direction of the needle. When the angulated tip of the device is judged to be directed at the distal vessel lumen and separated from it by not more than 1 to 2mms, the safety spacer (if fitted between hub items 7 and 15 in Figures 1 and 2) is removed and the hub 4 of 1 is advanced to the second clickstop of hub items 7 and 15, shown in Figures 1 and 2. This advances the tip A of 1 through the intimal layer to a position approximately 4mm, X in Figure 1, beyond the tip E in Figure 1 of catheter 3 and into the distal vessel lumen. Collar 5 of 1 is now fully secured to male component 9 on hub 8 of 2 in Figures 1 and 2. (An arrangement of 7 and 15 in Figures 1 and 2 may be utilised whereby there are multiple clickstops (not illustrated) indicating varying degrees of extension of tip A of 1).

If there is free return of arterial blood through the hub assembly, 0.38mm (or similar) guidewire passage can now be attempted. Alternatively, a small contrast injection can be made through the lumen of 1 via hub 16, Figure 1, to determine the position of A, Figure 1. If tip A placement is not satisfactory, the collar 5 on hub 4 in Figures 1 and 2 is slackened allowing the inner needle tip A to be withdrawn into the retracted position (first clickstop position of 7 and 15 in Figures 1 and 2). Following careful repositioning of the transintimal recanalisation device as above, further attempts may be made to enter the lumen. The small diameter of 1 reduces the risks of damage to collateral vessels and target vessel perforation. It is however stressed that significant force must not be used and the procedure must not be progressed if the inner needle tip A is not within the distal vessel lumen.

Where the position of tip A of 1 is judged satisfactory, the 0.38mm guidewire is advanced beyond tip A of 1, with gentle torque if necessary, and into the distal vessel lumen. Passage of the wire is facilitated by the constant orientation distally, as B in Figure 1 of the needle bevel. When the 0.38mm wire position is judged satisfactory, collar 13 on hub 12 of catheter 3 in Figure 2 is released and the puncture device, comprising inner needle 1 and guide tube 2 secured together by collar 5 of hub 4, is removed over the wire as one unit and without withdrawing either catheter 3 or the wire.

It should usually be possible to now advance catheter 3 over the 0.38mm wire and into the target vessel lumen. This process may be facilitated by use of an inner, coaxial, recanalisation catheter (not illustrated) which is passed over the wire, through the outer catheter 3. The inner recanalisation catheter, if used, is longer than catheter 3, allowing passage of inner recanalisation catheter into the distal lumen over the 0.38mm wire. Outer catheter 3 is then advanced over combined wire/inner catheter until tip of 3 lies in the distal vessel lumen.

The inner catheter and 0.38mm guidewire are now removed and contrast injection can be performed to confirm the position of 3 in the distal vessel lumen.

If position of 3 is judged to be satisfactory, a 0.86mm guidewire can be inserted and 3 exchanged for a conventional balloon catheter for angioplasty to be performed in the standard manner.

Claims

1. A flexible transintimal recanalisation device

adapted to be guided through the vasculature of the patient comprising a guide tube (2), a flexible needle (1) having a bevelled end (A) and located in said tube (2), wherein said needle (1) is movable from a covered position wherein said bevelled end (A) is within the tube (2) to an uncovered position in which said bevelled end (A) is exposed, and means enabling said bevelled end (A) to adopt a desired orientation with respect to the tube (2).

2. A device as claimed in claim 1, wherein said tube (2) has a bend (C) in its length and the needle (1) has a bend (C') in its length which conforms with the bend (C) of the tube (2), thereby orientating the bevelled end (A) with respect to the tube (2).

3. A device as claimed in claims 1 or 2, wherein said needle (1) is hollow.

4. A device as claimed in claims 1, 2 or 3 further comprising means for manoeuvering the needle with respect to the tube.

5. A device as claimed in claim 4, wherein said means for enabling said bevelled end (A) to adopt a desired orientation with respect to the tube (2) is provided by said manoeuvering means.

6. A device as claimed in claim 4 or 5, wherein said manoeuvering means comprises a first body (4) connected to an end of the needle (1) spaced from the bevelled end (A).

7. A device as claimed in claim 6, wherein said first body (4) is provided with a first aperture therethrough in communication with said hollow needle (1).

8. A device as claimed in claims 6 or 7 further comprising a second body (8) connected to an end of said tube (2) and wherein said second body (8) is provided with a first aperture therethrough to allow the passage of said needle (1).

9. A device as claimed in claims 7 or 8, wherein said first (4) and/or second body (8) has a second aperture extending from said first aperture to a surface of the body.

10. A device as claimed in claims 8 or 9, wherein said first and second bodies (4, 8) are provided with cooperating alignment means (7, 15) whereby cooperation of said means results in the bevelled end (A) of the needle (1) adopting a desired orientation.

11. A device as claimed in claim 10, wherein said alignment means comprises a cooperating protrusion (7) and recess (15).

12. A device as claimed in claims 8, 9, 10 or 11, wherein said first and second bodies (4, 8) have means for indicating the relative position of the bevelled end (A) of the needle (1) with respect to an end of the tube (2) spaced from said second body (8).

13. A device as claimed in claim 12, wherein said indicating means is provided by the cooperation of a protrusion with one of at least two spaced apart apertures.

14. A device as claimed in any one of claims 8 to 13, wherein said first and second bodies (4, 8) form a luer arrangement.

15. A device according to any one of claims 3 to 14, wherein said needle (1) and/or said tube (2) is or are formed from a material having shape memory properties such that the needle (1) or tube (2) will adopt said bend at a given temperature.

16. A device as claimed in claims 15, wherein said material is a nickel titanium alloy.

17. A method of assembling a flexible transintimal recanalisation device adapted to be guided through the vasculature of a patient having a guide tube (2), a flexible needle (1) having a bevelled end (A) and located in said tube (2), a body (4) connected to an end of the needle (1) spaced from said bevelled end (A) and means enabling the bevelled end (A) to adopt a desired orientation with respect to the tube (2) wherein said method comprises the steps of threading the end of the needle (1) spaced from said bevelled end (A) through the guide tube (2) until it extends beyond an end of the tube (2) and connecting said body (4) to the end of the needle (1).

18. A method of assembling a flexible transintimal recanalisation device adapted to be guided through the vasculature of a patient having a guide tube (2) with a bend (C) in its length, a flexible hollow needle (1) having a bevelled end (A) and located in said tube (2) and means enabling the bevelled end (A) to adopt a desired orientation with respect to the tube (2) wherein said method comprises the steps of threading a stylette into the tube until an end of the stylette extends beyond the bevelled end (A) of the needle (1), inserting the needle (1) and stylette into the tube (2) until a desired position is reached and withdrawing the stylette.

Patentansprüche

1. Flexible transintimale Rekanalisationseinrichtung, welche dazu geeignet ist, durch eine Gefässstruktur eines Patienten geführt zu werden, wobei sie eine Führungshülse (2), eine flexible Nadel (1), die ein abgeschrägtes Ende (A) aufweist und in der Führungshülse (2) angeordnet ist, wobei die Nadel (2) aus einer verdeckten Position, in welcher sich das abgeschrägte Ende (A) innerhalb der Führungshülse (2) befindet, in eine ungeschützte Position, in welcher das abgeschrägte Ende (A) frei ist, bewegbar ist, und eine Einrichtung umfasst, die dazu geeignet ist, dass das abgeschrägte Ende (A) eine gewünschte Ausrichtung im Hinblick auf die Führungshülse (2) annimmt.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Führungshülse (2) einen Kurvenabschnitt (C) auf ihrer Länge und die Nadel (1) einen Kurvenabschnitt (C) auf ihrer Länge aufweist, welcher mit dem Kurvenabschnitt der Führungshülse (2) übereinstimmt, wodurch die Ausrichtung des abgeschrägten Endes (A) im Hinblick auf die Führungshülse (2) erfolgt.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Nadel (1) hohl ist.

4. Vorrichtung nach Anspruch 1, 2 oder 3, welche ferner eine Einrichtung zum Lenken der Nadel im Hinblick auf die Führungshülse aufweist.

5. Vorrichtung nach Anspruch 4, dadurch gekennzeichnet, dass die Einrichtung, die dazu geeignet ist, dass das abgeschrägte Ende (A) eine gewünschte Ausrichtung im Hinblick auf die Führungshülse (2) annimmt, durch diese Lenkeinrichtung gebildet wird.

6. Vorrichtung nach Anspruch 4 oder 5, dadurch gekennzeichnet, dass die Lenkeinrichtung einen ersten Körper (4) aufweist, der mit einem dem abgeschrägten Ende (A) fernen Ende der Nadel (1) verbunden ist.

7. Vorrichtung nach Anspruch 6, dadurch gekennzeichnet, dass der erste Körper (4) mit einer ersten Öffnung versehen ist, durch die er in Verbindung mit der hohlen Nadel (1) steht.

8. Vorrichtung nach Anspruch 6 oder 7, welche des weiteren einen zweiten Körper (8) aufweist, der mit einem Ende der Führungshülse (2) verbunden ist, wobei der zweite Körper (8) mit einer ersten Öffnung versehen ist, durch die ein Durchfuhren der Nadel (1) gewährleistet ist.

9. Vorrichtung nach Anspruch 7 oder 8, dadurch gekennzeichnet, dass der erste (4) und/oder zweite Körper (8) eine zweite Öffnung aufweist, welche sich von der ersten Öffnung zu einer Oberfläche des Körpers erstreckt.

10. Vorrichtung nach Anspruch 8 oder 9, dadurch gekennzeichnet, dass die ersten und zweiten Körper (4, 8) mit zusammenwirkenden Ausrichtelementen (7, 15) versehen sind, wobei das Zusammenwirken dieser Elemente dem abgeschrägte Ende (A) der Nadel (1) ermöglicht, eine gewünschte Ausrichtung anzunehmen.

11. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, dass die Ausrichtelemente einen mit einer Einformung (15) zusammenwirkenden Vorsprung (7) aufweist.

12. Vorrichtung nach Anspruch 8, 9, 10 oder 11, dadurch gekennzeichnet, dass die ersten und zweiten Körper (4, 8) Einrichtungen zum Anzeigen der relativen Position des abgeschrägten Endes (A) der Nadel (1) im Hinblick auf ein Ende der Führungshülse (2) räumlich getrennt von dem zweiten Körper (8) aufweisen.

13. Vorrichtung nach Anspruch 12, dadurch gekennzeichnet, dass die Anzeigeeinrichtung durch das Zusammenwirken eines Vorsprunges mit einer von zumindest zwei räumlich getrennten Öffnungen gebildet ist.

14. Vorrichtung nach einem der Ansprüche 8 bis 13, dadurch gekennzeichnet, dass die ersten und zweiten Körper (4, 8) eine Passitzanordnung ausbilden.

15. Vorrichtung nach einem der Ansprüche 3 bis 14, dadurch gekennzeichnet, dass Nadel (1) und/oder Führungshülse (2) aus einem Werkstoff geformt ist oder sind, der bezüglich der Form Erinnerungseigenschaften aufweist, so dass die Nadel (1) oder Führungshülse (2) diesen gekrümmten Abschnitt bei einer vorgegebenen Temperatur annehmen wird.

16. Vorrichtung nach Anspruch 15, dadurch gekennzeichnet, dass der Werkstoff eine Nickel-Titan-Legierung ist.

17. Verfahren zum Zusammensetzen einer flexiblen transintimalen Rekanalisationeinrichtung, welche dazu geeignet ist, durch eine Gefässstruktur eines Patienten geführt zu werden, mit einer Führungshülse (2), einer flexible Nadel (1), welche ein abgeschrägtes Ende (A) aufweist und in der Führungshülse (2) angeordnet ist, einem Körper (4), welcher mit einem dem abgeschrägten Ende

(A) fernen Ende der Nadel verbunden ist, und einer Einrichtung, die es ermöglichen, dass das abgeschrägte Ende (A) eine gewünschte Ausrichtung im Hinblick auf die Führungshülse (2) annimmt, dadurch gekennzeichnet, dass das Verfahren die Schritte umfasst, das dem abgeschrägten Ende (A) ferne Ende der Nadel (1) durch die Führungshülse (2) einzusetzen, bis es sich über das Ende der Führungshülse (2) hinaus erstreckt, und den Körper (4) mit dem Ende der Nadel (1) zu verbinden.

18. Verfahren zum Zusammensetzen einer flexiblen transintimalen Rekanalisationsvorrichtung, welche dazu geeignet ist, durch die Gefässstruktur eines Patienten geführt zu werden, welche eine Führungshülse (2) mit einem abgebogenen Bereich (C) auf ihrer Länge, eine flexible hohle Nadel (1), welche ein abgeschrägtes Ende (A) aufweist und in der Führungshülse (2) angeordnet ist, und eine Einrichtung aufweist, welche es ermöglicht, dass das abgeschrägte Ende (A) eine gewünschte Ausrichtung im Verhältnis zu der Führungshülse (2) annimmt, dadurch gekennzeichnet, dass dieses Verfahren die Schritte umfasst, eine Sonde in die Führungshülse einzubringen, bis ein Ende der Sonde sich über das abgeschrägte Ende (A) der Nadel (1) hinaus erstreckt, die Nadel (1) und die Sonde in die Führungshülse (2) einzusetzen, bis eine gewünschte Position erreicht ist, und die Sonde zurückzuziehen.

Revendications

1. Un dispositif flexible de recanalisation transintima susceptible d'être guidé à travers le système vasculaire du patient, comprenant un tube guide (2), une aiguille flexible (1) présentant une extrémité biseautée (A) et disposée dans ledit tube (2), dans lequel ladite aiguille (1) est mobile depuis une position couverte dans laquelle ladite extrémité biseautée (A) est à l'intérieur du tube (2), jusqu'à une position découverte pour laquelle ladite extrémité biseauté (A) est exposée, et des moyens permettant à ladite extrémité biseautée (A) de prendre une orientation souhaitée par rapport au tube (2).

2. Un dispositif selon la revendication 1, dans lequel ledit tube (2) présente un coude (C) sur sa longueur et l'aiguille (1) présente sur sa longueur un coude (C'), qui se conforme au coude (C) du tube (2), de manière à orienter l'extrémité biseauté (A) par rapport au tube (2).

3. Un dispositif selon les revendications 1 ou 2 dans lequel ladite aiguille (1) est creuse.

4. Un dispositif selon les revendications 1, 2 ou 3, comprenant en outre des moyens pour manoeuvrer l'aiguille par rapport au tube.

5. Un dispositif selon la revendication 4, dans lequel lesdits moyens pour permettre à ladite extrémité biseautée (A) de prendre une orientation souhaitée par rapport au tube (2), sont constitués par lesdits moyens pour manoeuvrer.

6. Un dispositif selon la revendication 4 ou 5, dans lequel lesdits moyens pour manoeuvrer comportent un premier corps (4) relié à une extrémité de l'aiguille (1) et placé à distance de l'extrémité biseautée (A).

7. Un dispositif selon la revendication 6, dans lequel ledit premier corps (4) est muni d'une première ouverture le traversant et en communication avec ladite aiguille creuse (1).

8. Un dispositif selon les revendications 6 et 7, comprenant en outre un deuxième corps (8) relié à une extrémité dudit tube (2), et dans lequel ledit deuxième corps (8) est muni d'une première ouverture le traversant pour permettre le passage de ladite aiguille (1).

9. Un dispositif selon les revendications 7 ou 8, dans lequel lesdits premier (4) et/ou deuxième corps (8) présentent une deuxième ouverture s'étendant depuis ladite première ouverture jusqu'à une surface du corps.

10. Un dispositif selon les revendications 8 ou 9, dans lequel lesdits premier et deuxième corps (4, 8) sont munis de moyens d'alignement coopérants (7, 15), de telle manière que la coopération desdits moyens ait pour résultat que l'extrémité biseautée (A) de l'aiguille (1) adopte une orientation souhaitée.

11. Un dispositif selon la revendication 10, dans lequel lesdits moyens d'alignement comportent une partie en saillie coopérante (7) et une cavité (15).

12. Un dispositif selon les revendications 8, 9, 10 ou 11, dans lequel lesdits premier et deuxième corps (4, 8) comportent des moyens pour indiquer la position relative de l'extrémité biseautée (A) de l'aiguille (1) par rapport à une extrémité du tube (2) espacée dudit deuxième corps (8).

13. Un dispositif selon la revendication 12, dans lequel lesdits moyens d'indication sont constitués par la coopération d'une partie en saillie avec l'une parmi au moins deux ouvertures espacées l'une de l'autre.

14. Un dispositif selon l'une quelconque des revendications 8 à 13, dans lequel lesdits premier et

deuxième corps (4, 8) forment un agencement de luer.

15. Un dispositif selon l'une quelconque des revendications 3 à 14, dans lequel ladite aiguille (1) et/ou ledit tube (2) est/sont formé(s) en un matériau présentant des propriétés de mémoire de forme, de telle façon que l'aiguille (1) ou le tube (2) adopte ledit coude à une température donnée.

16. Un dispositif selon la revendication 15, dans lequel ledit matériau est un alliage nickel titane.

17. Un procédé d'assemblage d'un dispositif flexible de recanalisation transintima susceptible d'être guidé à travers le système vasculaire d'un patient, présentant un tube guide (2), une aiguille flexible (1) munie d'une extrémité biseautée (A) et disposée dans ledit tube (2), un corps (4) relié à une extrémité de l'aiguille (1) espacée de ladite extrémité biseautée (A), et des moyens permettant à l'extrémité biseautée (A) d'adopter une orientation souhaitée par rapport au tube (2), dans lequel ledit procédé comporte les étapes consistant à visser l'extrémité de l'aiguille (1) espacée de ladite extrémité biseautée (A) à travers le tube guide (2) jusqu'à ce qu'elle s'étende au-delà d'une extrémité du tube (2) et à relier ledit corps (4) à l'extrémité de l'aiguille (1).

18. Un procédé d'assemblage d'un dispositif flexible de recanalisation transintima susceptible d'être guidé à travers le système vasculaire d'un patient, présentant un tube guide (2) muni d'un coude (C) sur sa longueur, une aiguille creuse flexible (1) présentant une extrémité biseautée (A) et disposée dans ledit tube (2) et des moyens permettant à l'extrémité biseauté (A) d'adopter une orientation souhaitée par rapport au tube (2), dans lequel ledit procédé comporte les étapes consistant à visser un stylet à l'intérieur du tube, jusqu'à ce qu'une extrémité du stylet s'étende au-delà de l'extrémité biseauté (A) de l'aiguille (1), à insérer l'aiguille (1) et le stylet dans le tube (2) jusqu'à ce qu'une position souhaitée soit atteinte et à retirer le stylet.

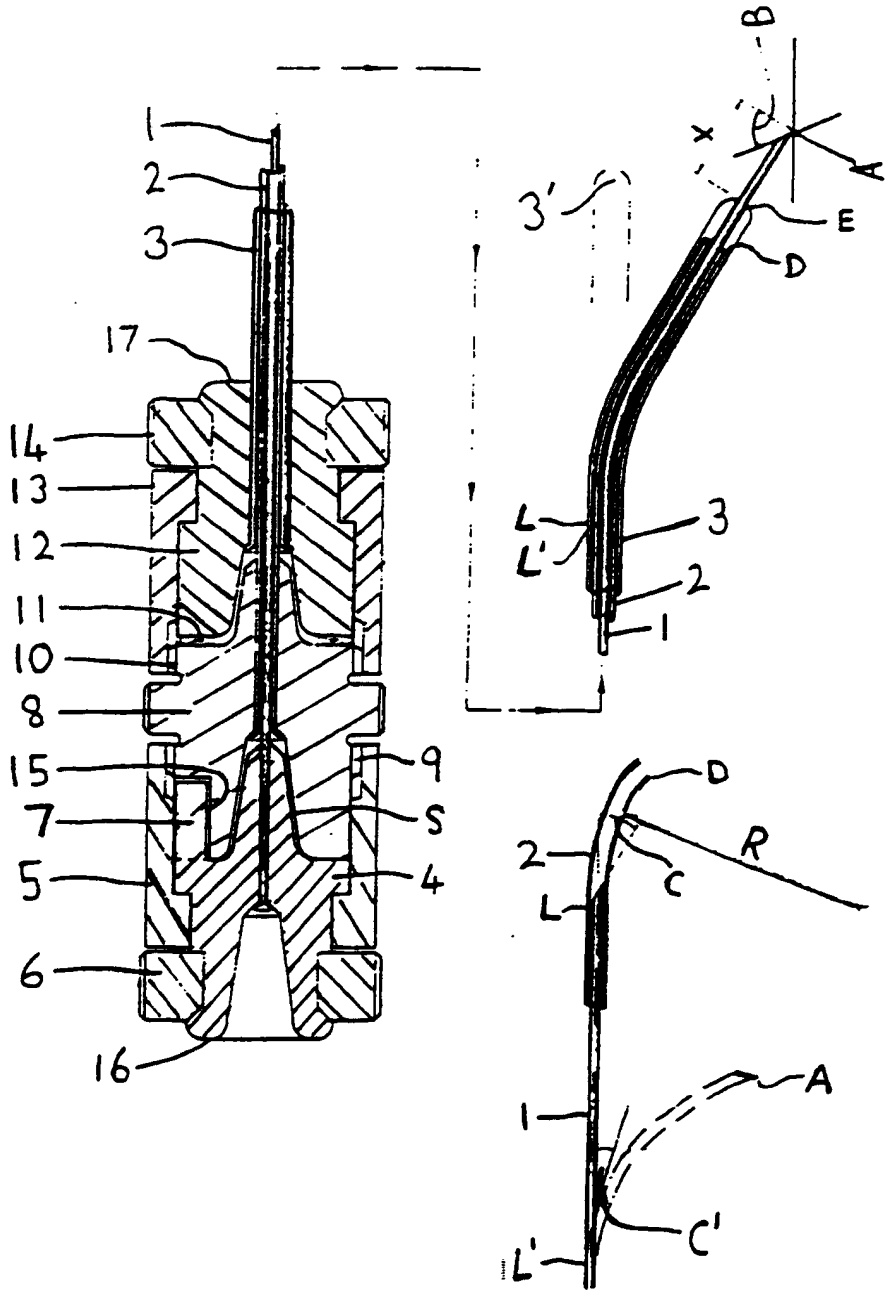

Fig. 1

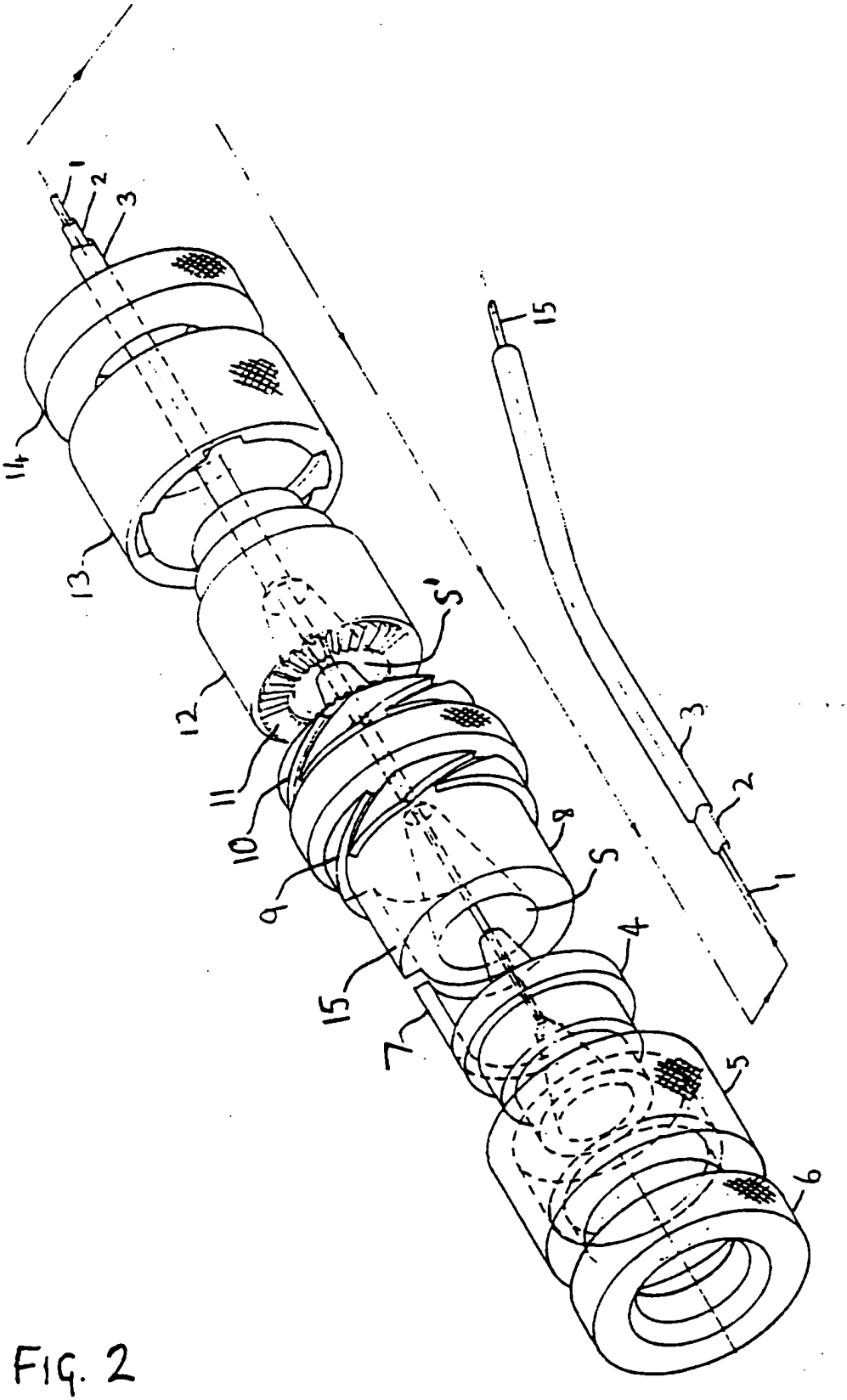

FIG. 2